American Chemistry Council | Biocides Panel

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Examples of Regulation by Guidance or Unwritten Policies

The Biocides Panel (Panel) is concerned that the US Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) and Antimicrobials Division (AD) continue to develop and implement new or changed policies with no process surrounding the changes and no public documentation released in advance. We note that while many of the specific examples set forth in this paper have been resolved, EPA needs to address its processes so these types of issues do not continue to occur.

Too often, the first time companies become aware of a change in AD policy or requirements is through individual product registration decisions. EPA also has tried to implement draft, not final, policy and guidance documents that represent changes in policy.

New policies that are developed without input from all interested registrants often create unnecessary implementation issues and can be based on an incomplete understanding of the impacts. This is particularly problematic in those situations in which a policy is implemented as part of an individual registration decision and there is no notice to registrants at-large of the change. In addition to the lack of transparency and the inability for all community at-large to comment on the policy, an uneven playing field is created (where some registrants are required to make changes that adversely impact them compared to competitors). Those individual registrants impacted often expend significant resources to obtain relief, and then incur extra costs to obtain a new approval once the policy is overturned or modified. The costs and effort associated with state approvals compound the problems.

The following examples reflect shifts in a significant EPA policy or practice for antimicrobials that was discussed only within an EPA document without a clear associated notice or comment period. The Panel is not advocating rulemaking for all EPA actions, but rather, is asking that EPA recognize the impact of certain guidance by making the entire registrant community aware of it in advance of implementation and providing their rationale through a notice in the *Federal Register,* via the OPP website, or other public mechanism, with an associated opportunity for comment.

Example 1: Potable Water Rinse

AD recently expanded the scope of its dietary risk assessments for antimicrobial pesticides, including both active and inert ingredients. Without any public documentation or process, the Agency has set aside both its own and the Food and Drug Administration's (FDA) longstanding approach to potable water rinse (PWR) and adopted a new regulatory interpretation that imposes burdens on both EPA and registrants with no corresponding benefit.

EPA has not publicized its rationale for this change in position or for its sudden implementation – no public process has taken place. Notice of the change of the PWR approach has only

occurred in meetings and discussions with certain trade associations and by a letter directed to only the Biocides Panel. EPA representatives have said in meetings with the Panel, and in a letter to the Panel on November 15, 2016, that data submitted showing measurable residues of one active ingredient following a potable water rinse underlie its new position. However, there is no public documentation of EPA's change in position. In this particular case, the Panel would argue that notice and comment rulemaking is required because of the significant regulatory consequences associated with the policy.

AD has failed to acknowledge the magnitude of its change, seek input on the issue of whether the new approach it is taking is appropriate or, most importantly, to consider alternative approaches based on existing science. Instead, AD unilaterally has asserted that an antimicrobial for use on hard surfaces, even if followed by a PWR, is a food use unless the registrant demonstrates "no reasonable expectation of residues." AD has not provided any guidelines on what the "no reasonable expectation of residues" means, and, as such, we have to assume it is zero (0). EPA fails to acknowledge that proving a zero residue is scientific impossibility. FDA, and even EPA until recently, has applied *de minimis* thresholds for decades. EPA needs to reestablish a *de minimis* threshold.

Example 2: Proposed Change to the Use of Terms "Biofilm" and "Slimicide"

Long-standing EPA policy allowed the terms "biofilm" and "slimicide" to be used interchangeably. Within a 2016 draft guidance for testing procedures for public health claims associated with biofilms titled *Guidance to Assess the Efficacy of Antimicrobial Pesticide Products Intended to Control Public Health Biofilms on Hard, Non-Porous Surfaces* (announced as an OPP Update), EPA stated that the term "biofilm" would be limited to public health claims, and the term "slimicide" would be required for all non-public health uses.[1] Announcing a change on allowable claims in an efficacy guidance document is not appropriate. Also, it was inappropriate that during the same time, EPA was requiring removal of the term "biofilm" on labels for non-public health uses as part of individual registration decisions, even for label amendments unrelated to that particular area.

The Panel has been assured by EPA that the term "biofilm" will not be limited to public health claims as set forth in the draft guidance and EPA will revert to the historical position where the terms "biofilm" and "slimicide" can be used interchangeably, but no official guidance has superseded the 2016 draft. Nevertheless, the process by which this issue arose should be reformed to ensure situations such as this do not reoccur.

Example 3: Implementation of Draft Mold Policy

In 2016, as part of individual registration actions, certain registrants were informed by EPA that it was implementing a 2012 draft policy on mold as internal policy. The EPA was forced to reverse itself when it became clear that it was not only inappropriate to implement the policy when comments had not been addressed and the policy had not been finalized, but also because

[1] *Draft Guidance to Assess the Efficacy of Antimicrobial Pesticide Products Intended to Control Public Health Biofilms on Hard, Non-Porous Surfaces*. Document EPA-HQ-OPP-2016-0357-0005. See [HYPERLINK "https://www.epa.gov/pesticides/two-proposed-test-methods-and-guidance-antimicrobial-efficacy-testing"].

the policy was flawed. There has been no additional comment from the Agency with regard to this issue yet product label reviews have been influenced by this proposal resulting in the rejection of label revisions by prospective registrants.

Example 4: Identification of Approved Alternate Confidential Statements of Formula

In 2015, without any prior notice to registrants, AD initiated a project to ensure its records regarding confidential statements of formula (CSFs) are up to date and accurate. Specifically, EPA began to identify what it considered to be a comprehensive list of accepted CSFs (basic and alternate) in response letters to registrants associated with unrelated registration actions. EPA's position was that *only* those CSFs listed in the EPA response letter are approved. This meant that if the listing was incorrect or incomplete, EPA inappropriately attempted to invalidate a license/approval/etc. just because it could not find a copy of the approval in its records with no opportunity for a registrant to correct the Agency before that position was final. Despite the impact this policy had on registrants, there was no prior opportunity to review the accuracy of EPA's listing. Mistakes, and there were many, had to be resolved through a laborious effort of resubmitting the CSFs and documentation of EPA's prior approval. While the goal of EPA's exercise was important, the manner in which it was implemented created an unreasonable and unexpected workload for many registrants. EPA should have notified the registrant community of its intentions and solicited input on an appropriate process to verify its records.

Example 5: Inert Ingredient Listings

Over time, there has been dramatic inconsistency in EPA's approach to the listing of inert ingredients on CSFs. Questions arise because of unstated "policy" (in at least one situation, developed and implemented by a single reviewer within AD) while other issues arise due to policies that vary among reviewers and from year to year. Registrants who do not follow the requirements of the individual reviewer do not obtain approval for the CSF. "Unique" requirements have included:

- Requiring that a trade name be used for an ingredient of known composition (such as a single compound in an aqueous solution) rather than just listing the CAS No.;
- Requiring that trade names be added by the inert supplier to the *voluntary* trade name data base (even if the inert ingredient is not a proprietary blend); and
- Not allowing the use of an approved inert ingredient because the ingredient did not yet appear in the EPA database even when the registrant provides documentation of its prior approval.

EPA's handling of "commodity" inerts also has been inconsistent over the years.

Resolving these and similar issues can involve significant time and effort and can result in registrants needing to reapply even when there is clear documentation of the acceptability. EPA should reform its process to ensure clarity as to inert listing requirements and make changes to those requirements only following advance notice and opportunity for registrant input.

Example 6: Allowable Claims and Label Uses

Particularly for products with public health claims, EPA has changed what types or levels of claim are acceptable. These changes have occurred by individual product label review/registration actions, yet these decisions significantly modify for the full registrant community what previously was permitted. A few of many examples are shown below:

- Panel members report that EPA has changed its policy regarding allowable claims for toilets based upon germicidal spray test data. EPA has registered numerous products that claim effectiveness "above the water line" claim or include directions to empty the bowl prior to disinfection. EPA apparently is no longer allowing these label claims. This is a shift in policy (and a deviation from current 810s). One Panel member learned of this new EPA policy in a letter requiring this change as a label update required to close out a registration action.
- EPA no longer allows "99.99%" reduction claims for disinfection when supported by qualitative test methods (e.g. AOAC Use-Dilution, AOAC Germicidal Spray Test for sprays/towels, AOAC TB Test, AOAC Fungicidal Test), even though the 99.99% claim has been allowed for over a decade based on the requirement for these studies to demonstrate at least 4 log/carrier.
- In connection with a new registration, EPA sought to impose a new interpretation of guideline 810.2300 that would raise the performance criteria for halogen food contact sanitizers to equivalence to the 200ppm chlorine control in the AOAC Chlorine Equivalence Test rather than the historical interpretation and text requiring equivalence to either 50, 100, or 200ppm The historic approach also was consistent with the AOAC method, FDA Food Code, Health Canada guidelines, PPLS labels, DER from all registration actions for the past 10 years, and RED instructions. Further, the change could have made it impossible to use halogen-based products for food use where tolerance exemptions are established at 100 ppm, not at 200ppm.

  This situation appears to be resolved. However it highlights the importance of EPA implementing processes to ensure stability in allowable claims and associated test methods. Any changes should be subject to notice and comment prior to implementation.

Example 7: Alternate Formulation Process Under PR 98-10

EPA appears to have changed the procedure for processing an alternate formulation from a notification (per PR Notice 98-10) to a PRIA action and its associated fees (action code A570: Label amendment requiring data review). PR Notice 98-10 permits modification of the formulation process *via* notification as stated in section III (Product Chemistry Notifications) D (Change in Formulation Process):

> A registrant may modify a formulation process of a product made by a non-integrated system (a blending or dilution of product components involving no chemical reaction—distinguished from a reaction process), provided:

The certified limits of the active and inert ingredients do not change as a result; and
The physical/chemical/biological characteristics and/or the effectiveness (efficacy) of the product will not change.

Unless and until it revises PR Notice 98-10, EPA should ensure that it complies with its own guidance.

Example 8: Requirement for New and Unclear Methods for Determining Whether an Ingredient Should be identified as an Active Component

EPA has no written guidance on how to determine whether an ingredient is considered active or inert. Inert ingredients (e.g. surfactants, preservatives, pH balancers) may have measurable but insignificant antimicrobial activity depending on the test used to assess the activity. Historically, EPA requested testing in the EPA-required efficacy test method used to register the product (e.g. AOAC UDM) using the required test organisms with the full formulation alongside a test lot made without the known active ingredient (AI) (expected to fail if the unknown ingredient was inactive), or without the unknown ingredient (expected to pass if the unknown ingredient was not Active). Recently, without prior notice or documentation, EPA has begun requiring testing using Minimum Inhibitory Concentration (typically used for antibiotic testing for drug uses) even though:

- The method is not used to support label claims.
- The MIC 24 hour contact time is not relevant to the use directions for the registered product.
- The MIC test is measuring "inhibition" of bacteria, not kill. The products involved are public health products requiring the demonstration of kill.
- EPA has not defined the performance criteria to be applied to the results to determine if an ingredient is active.
- The MIC test does not have a published procedure recognized by EPA.
- The MIC test does not have required test organisms and nor has EPA defined them.
- The growth media may interact with the formulation causing spurious or inconsistent results.